IMPACT OF TRAINING ON STEROIDAL MODULE OF ATHLETE BIOLOGICAL PASSPORT AMONG INDIAN ATHLETES

SHORT SYNOPSIS

Submitted in partial fulfillment of the requirement of the degree of

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Certificate

I hereby declare that the short synopsis "Title: **Impact of Training on Steroidal Module of Athlete Biological Passport among Indian Athletes**" being submitted in partial fulfillment of the requirement for the degree of Doctor of Philosophy in the Department of **Biochemistry** under the **School of Allied Health Sciences** of Manav Rachna International Institute of Research and Studies, Faridabad during the academic year **2021**. It is a bona fide record of original work carried out under the supervision of **Dr. Anjana Goyal** and has not been submitted in full or part to any other university or institute for a degree or diploma. Further, it is certified that Short Synopsis is plagiarism-free, and the proof has been submitted.

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ABSTRACT

Athlete Biological Passport (ABP) tracks biological indicators over time to gather the effects of doping without directly identifying the substances and methods that are being used. This new strategy involved switching from the direct finding of a prohibited drug in a biological sample to the finding of anomalies in direct and & or indirect bio indicators capable of possibly exposing the existence of doping[1]. It is currently unknown whether training (exercise) can change the steroidal markers listed in the biological passport in a way that the variations could be misinterpreted for manipulation. The focus of the proposed study is to ascertain the impact of an athlete's training load on the steroidal module of their biological passport. For this purpose, athletes' urine samples will be periodically taken during the periodization training cycle, which includes preparatory, pre-competition, competition & transition phases. At a laboratory that is accredited by the World Anti-Doping Agency (WADA), the sample will be analyzed. As per the protocol outlined in the WADA technical document, GC-MS shall be used to quantify the markers of the steroid profile. Univariate statistical analysis utilizing one-way ANOVA will be employed, along with a Bayesian model for data interpretation.

Keywords: Athlete Biological Passport, Athlete, Athlete Passport Management Unit, Steroidal module, Training & World Anti-Doping Agency.

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DESCRIPTION OF THE BROAD AREA

1.1 INTRODUCTION

The primary purpose behind the Athlete Biological Passport (ABP) program is to track specific biological parameters strenuously to detect the effects of doping without clearly sensing the drug or technique that is being used. Its exclusive method was to shift from the straightforward detection of banned substances or methods in a sample to the detection of anomalies, direct and indirect bio-indicators that are capable of revealing the presence of doping. *(Sottas et al., 2011)*.

The phrase ABP was initially used by experts from the anti-doping community in the early 2000s, once they were tracking hematological variables over time to find evidence of blood doping. The World Anti-Doping Agency (WADA) took the lead in helping to further develop, unify, and validate the concept in collaboration with partners and medical specialists. As a result, WADA released its first set of athlete biological passport operational instructions for anti-doping organizations and international federations in 2009 to assist them in implementing the hematological module.

In the year 2014, the World Anti-Doping Agency introduced a steroidal module to complement the above component, which aims to create the longitudinal profile of an athlete's steroidal profile in urine. As of 2023, steroidal variables are also being introduced in the blood (serum) to complement the urine testing. *(WADA ABP Operating Guidelines, 2021).* Furthermore, WADA introduced the endocrine module, which focuses on detecting markers of human Growth Hormone (hGH).

The ABP program combines statistical analysis of test findings with human interpretation of passport data. The ABP can be used for deterrence through intelligence, sanctions, and health protection. The primary objectives of incorporating the ABP in the greater context of an active anti-doping program are as follows. First, ABP can be used to identify the athletes who require additional consideration by intelligently interpreting passport data in real time. The ABP provides essential information that can be used for better, intelligent, target-based testing. athlete biological passport can be used in combination with analytical procedures to develop and strengthen comprehensive anti-doping approaches such as the hematological module, which includes testing of homologous blood transfusion, erythropoiesis-stimulating agents, etc. Secondly, the steroidal module includes gas chromatography combustion isotope ratio mass spectrometry (GC-C-IRMS) to distinguish between endogenous and exogenous steroids. Further, an athlete biological passport can be used to follow up on a rule violation as mentioned under the WADA Code. This can also be used to confirm the presence of a

prohibited substance or marker without relying solely on the detection of a specified prohibited substance or method. This technique has proven highly effective in detecting anti-doping rule violations without typical analytical procedures *(WADA Athlete Biological Passport Operating Guidelines, 2021).* Third, the ABP can be used to preserve one's health because it gives a clear picture of how doping affects an athlete's physiology. Because doping leaves a biological imprint, it can also be used to prevent others because athletes can no longer cheat without consequences.

The implementation of the blood passport process is complex due to the large number of participants and individuals involved, implementing the blood passport process is complicated. First, anti-doping organizations (ADOs) use the given data to determine "who, when, and what" to test. Athletes enter their location into the anti-doping administrative management system (ADAMS), and anti-doping organizations frequently collect blood samples. Sample collection and chain of custody criteria must be followed by doping control officers, and phlebotomy is the responsibility of blood control officers. Blood samples are transported by couriers to the WADA-accredited laboratories for blood analysis.

The passports created from data generated on ADAMS are managed by an expert, the ADOs, to determine whether athletes have questionable profiles. The passports must next be examined by an international specialist to evaluate whether unusual or suspicious passport profiles are caused by doping or a medical condition. The ADOs conduct a disciplinary hearing when all requirements for an adverse passport finding are met, at which point the legal community becomes involved *(Robinson, N et. al, 2011).*

Currently, there are three types of modules studied in the Athlete Biological Passport:

(a) Hematological Module

The hematological module gathers data on blood doping markers, which are used to detect the use or presence of banned substances and methods that enhance blood oxygen carriage or transfer capacity, including the use or presence of erythropoietin-stimulating agents and any kind of blood transfusion.

Along with the detection of substances, this module also tries to determine the use of methods listed in the prohibited list. In addition to the aforementioned markers, other blood parameters are also measured within the athlete biological passport’s hematological module.

The hematological adaptive model is built on a system that considers athlete data gathered over time and calculates individual limits, enabling the identification of abnormal blood profiles that may be indicative of doping. The optimized flow of fluid (OFF)-hr score, derived from Hb & Ret %, is used to establish the adverse finding cases up to four weeks after the discontinuation of rh EPO treatment and is one of the two primary

markers of the adaptive model *(Gore, C. J et al, 2003)*. A supplementary marker of the athlete biological passport, the abnormal blood profile score, is also included in the athlete biological passport computation program. It is derived from several hematological data.

(b) Steroidal Module

The steroidal module aims to detect the exogenous use of endogenous anabolic androgenic steroids, as well as other anabolic drugs, including selective androgen receptor modulators, that are on the prohibited list. The Steroidal module can also be utilized to identify samples that have been manipulated, tampered with, or swapped with the urine of another person. The above module considers the following markers, as defined in the procedural document for endogenous anabolic androgenic steroid (EAAS) indicators of the steroid profile. The following indicators are measured within the steroidal module are testosterone, androsterone, epitestosterone, etiocholanolone, 5α adiol, 5βadiol, and the subsequent ratios a/t, t/e, 5αadiol/5βadiol, a/etio & 5αadiol/e.

An athlete's steroidal passport is made up of the steroid profiles of various urine samples that were taken throughout time from that athlete. When synthetic EAAS is administered, one or more of the indicators in the urine steroid profile can change, either increasing or decreasing the quantity & or ratios of sets of steroid indicators. This results in the rationale behind steroidal passport use as a means for the detection of EAAS doping. Particularly, testosterone (T), its metabolite dihydrotestosterone (DHT), or its epimer epitestosterone—all of which are used as markers—can be detected using the steroidal Passport (E). This module of the ABP utilizes ADAMS's Adaptive Model to identify atypical passport findings, which may trigger the implementation of a confirmation procedure, the collection of an additional sample from the athlete, or the determination of the use of a prohibited substance *(WADA ABP Operating Guidelines, 2021)*.

The administrative portion of this program is handled by the athlete biological passport monitoring unit (APMU), which is connected to the laboratories performing the analysis. This ensures an unbiased assessment of the passport outcomes and the proper follow-ups. This suggests a means for individualized scrutiny and precise test scheduling, organizes records, compiles analytical reports, makes preliminary determinations, and collaborates for a thorough evaluation of passport data between independent specialists & ADOs. Any unfavorable passport reports must be reported by the APMU to the ADOs. APMU reviews any previous reports of athletes linked to passports, assesses the consistency of each sample, and updates the report as required. It assesses the need for target-oriented testing & informs the ADO of its proposal in the APMU report. It evaluates the necessity for more study by using various analytical techniques on samples that have already been collected. The report from the APMU is a crucial component of the administrative process for the ABP that is entered &

handled in the ADAMS *(WADA Athlete Passport Management Unit Requirements and Procedures, 2019).*

In this study, we explore the effects of different phases of training on the steroidal module of the ABP. There is currently uncertainty regarding whether training load as an external co-factor can affect the steroidal variables measured in the Athlete Biological Passport, potentially leading to a false indication of manipulation. Several outside cofactors are known to affect the outcomes of these markers. However, there is still a need to standardize the approach to accounting for training load. Most of the currently available studies have investigated the impact of training on the hematological module of ABP and were conducted for short durations only. No relevant study has available/conducted to see the impact of training load on the steroidal module of ABP.

1.2 DESCRIPTION OF THE TOPIC

ABP is to detect the particular biological parameters over the period that may indirectly disclose the effects of doping on the human body. The profile for each athlete is created based on arithmetical tools that use facts from every athlete's earlier sample to envisage the likely individual boundaries for future samples. If any information from a sample falls outside of the athlete's range, this irregular value may be a sign of doping or an external condition. This can also be used to conduct target-oriented testing on athletes with irregular profiles. ABP data can also serve as corroborating evidence of doping in anti-doping rule violation cases. Currently, the ABP program employs three modules: hematological, steroidal, and endocrine modules.

The proposed study focuses on the biomarker of the steroidal module in the urine of ABP, which includes the following biomarkers:

Markers	**Ratios**
Androsterone (A),	**T/E,**
Etiocholanolone (Etio),	**A/T,**
5α Adiol,	**A/Etio,**
5βAdiol,	**5αAdiol/5βAdiol**
Testosterone (T),	**5αAdiol/E.**
Epitestosterone (E)	**-----**

LITERATURE REVIEW

A Literature review is a very important part of any research study, which offers an overview of the past studies conducted on the topic, what are their methodology, findings, and it also helps researchers to identify the gap areas of the studies. Accordingly, for the present study, through literature review was conducted using Google Scholar, PubMed, Science Direct, and Google search engines, which involves examining review articles, original research articles, and books. The search terms include Athlete Biological Passport in combination with training, and the steroidal module were used.

The review is divided into sub-sections as follows:

2.1 Effect of training on physical parameters

2.2 Effect of training on different modules of Athlete Biological Passport

2.3 Role of co-factors on Athlete Biological Passport.

2.1 Effect of training on physical parameters

During the literature review, the effect of training on physical parameters was examined. Accordingly, it was found that in 2022, *Zhi-Chen et al.* investigated the effects of intense training on physical parameters related to hormonal levels in young athletes. The study concluded that basketball training can improve the aerobic capacity of young athletes. Furthermore, the research found a strong correlation between young people's physical fitness and variations in their blood hormone levels. In 2021, *Astolfi et al.* examined the influence of acute and chronic training on the Athlete Biological Passport variables in Elite Cyclists, and specific hematological changes were detected. It was found that all Athlete Biological Passport parameters remained within the individual's established limits. In 2014, *Bonne et al.* investigated, altitude training causes hematological fluctuations with relevance for the Athlete Biological Passport, which is appraised in top-level swimmers. Although it can be a mystifying feature for the Athlete Biological Passport description for up to 4 weeks subsequent to introduction, training at altitude does not always result in anomalous Athlete Biological Passport findings.

In 2014, Schumacher *et al.* examined the impact of immediate heavy exercise and high altitude contact on the controlled processes of the passport. In short, the anomalies detected in the hematological module of professional athletes during heavy exercise at high altitudes are restricted and are aligned with predictable physiological changes.

2.2 Effect of training on different modules of Athlete Biological Passport

Accordingly, during the review of the effect of training on different modules of the Athlete Biological Passport was also examined, and it was found that in 2021, *Piper et al.* detected that an abnormal steroid profile is facilitated by analyzing urine concentrations and concentration ratios. Athlete Biological Passport steroidal module was included because of the population-based criteria' limited applicability due to the high inter-individual variability of both concentration and ratio. The passport made it possible to create reference ranges for steroid profile data that were unique to each athlete. In 2021, *Krumm & Faiss* established that natural changes of the Athlete Biological Passport parameters appear relatively low, likely due, at least in part, to the robust human homeostatic mechanisms of the human body. Moreover, it is still unclear whether environmental factors (such as exposure to heat or hypoxia) significantly impact hematological variability. Considering the body of research already in existence that seeks to define adaptive individual boundaries, the current Athlete Biological Passport paradigm seems relatively stable. In 2020, *Mahendru et al.* stated that the Athlete Biological Passport does not depend on the finding of a specific illegal matter but instead considers changes in biological indicators gathered throughout an athlete's career. Athletes can also be followed up on by continuously interpreting passport data. Although there are many benefits to implementing this program, there are several concerns that should be considered that could result in incorrect interpretation of passport data.

Consequently, in the year 2019, *Voss et al.* investigated whether a new, combined approach to hypoxia training could potentially trigger abnormal findings in the Athlete Biological Passport. In conclusion, it is highly doubtful that the current hypoxic experience procedure could lead to a condition that would be considered a rule violation according to the guidelines. In 2019, *Nolan et al.* explained the Athlete Biological Passport's purpose, what is documented on it with an emphasis on the hematological component, which can lead to natural alterations to it & talked about its application in proficient athletics. Such natural differences frequently happen during grand tours; nevertheless, more study is needed into what occurs during these many cycling races regarding the Athlete Biological Passport, in 2019, *Amante et al.* investigated the 198 samples taken from an unprofessional marathon athlete during 3 months leading up to an international championship, the study analyzed Athlete Biological Passport steroid profile in addition to dihydrotestosterone (DHT) and DHEA and the basal steroid profile was found to be altered in urine samples obtained subsequent moderate or vigorous exercise, as measured by cardiac frequency and/or distance run, with notable elevation of testosterone, epitestosterone, and 5-androstane-3,17-diol. In contrast, intense exercise did not appear to change the ratios of any steroid concentrations. It seems that the change in steroid profiles only persisted for a short time. These findings give a caution on the Athlete Biological Passport results acquired right after the competition.

2.3 Role of co-factors on Athlete Biological Passport

In the literature review, the role of co-factors on the Athlete Biological Passport was also examined, and it was found that in 2020, *Prakash et al.* highlight the challenges faced by the authorities, noting that the outcomes of an Athlete's Athlete Biological Passport profile may be influenced by various factors, leading to potential misinterpretation of the data. It is a crucial weapon in the war against doping. The enormous potential of the Athlete Biological Passport is demonstrated by recent advances in metabolomics. The best method to prevent athletes from using illegal substances is now the Athlete Biological Passport's continued advancement with close biological parameter analysis. In 2020, *Börjesson et al.* examined the potential identification of doping agents in self-reported users of anabolic androgenic steroids, both among men & women. It was shown that deviations in gonadotropins and hematological parameters were related to the last consumption of AAS in men, although these biomarkers were standard in women. This highlighted gender-centric modifications & parameters and the need for other biomarkers in female athletes.

In the year 2020, *Mullen et al.* investigated the analysis of multiple urine steroid profiles from athletes in Sweden and Norway to identify both intra- and interindividual variances of all steroids and proportions in the passport. Additionally, it was examined if inter-individual variances may be linked to elements including gender, sport type, age, day of the week, season, and whether the urine was taken during or after the competition. We demonstrate that there are elements noted in current doping tests that have a significant impact on steroid profiles. The athlete's sport classification and whether the urine sample was taken during or after competition were the 2 variables that had the most significant impact on the profile. Additionally, there were notable variations depending on the day of the week and season the urine sample was taken. More research should be done to determine whether these major changes are pertinent when tracking athletes intensely using the steroidal component of the Athlete Biological Passport. In 2019, *Ponzetto et al.* identified that the longitudinal method improved testosterone doping finding proficiencies in assessment with the previous testosterone/epitestosterone reference range of four, it is still exposed to several disadvantages, largely associated with the urinary medium and the diagnostic procedure used for the analyses.

Subsequently, in the year 2019, *Ekström et al.* examined the urinary steroid markers before 3 months of subsequent intake of an oral HC together with levonorgestrel & ethinylestradiol. Although individuals followed the same schedule for using contraceptives, it was shown that HC-mediated epitestosterone changes significantly & were linked to a useful T/C-supported polymorphism in CYP17A1. Additionally, these increases in epitestosterone were associated with the changes in gonadotropins and testosterone brought on by HC, showing that urine epitestosterone replicates the androgen load in HC-using women. In 2018, *Ameer et*

al. investigated that both non-elite and elite athletes use anabolic androgenic drugs in competitive sports at the senior and junior age levels. Exogenous anabolic steroid use altered the T/E ratio, raising its assessment over the usual range. This evaluation will discuss anabolic steroids, their side effects & health consequences in the settings of both athletic performance and physical development. It also offers a transitory assessment of the history of anabolic steroids as doping agents.

As observed in the literature review of the above studies, the problem statement and the gap areas were identified. Accordingly, the research hypothesis of the present study was constructed and presented in the synopsis.

PROBLEM STATEMENT

i. Currently, it is unclear whether training during different phases of a periodization cycle can affect the steroidal variables in urine included in the Athlete Biological Passport.

ii. Several external cofactors are known to affect the results of these markers. However, the way these cofactors are considered still needs to be standardized.

iii. Most of the currently available studies have investigated the impact of training on the hematological component of an Athlete Biological Passport, but these studies have been conducted over relatively short durations only.

iv. No relevant studies have been found or conducted to investigate the impact of training load during different phases of an athlete's training cycle on the steroidal module in the urine of the Athlete Biological Passport among Indian athletes

RESEARCH HYPOTHESIS

i. This study anticipates a significant impact of training interventions across various phases of the periodization cycle on the steroidal module found in the urine of Athlete Biological Passport among Indian athletes.

ii. This study anticipates no significant impact of training interventions across various phases of the periodization cycle on the steroidal module found in the urine of Athlete Biological Passport among Indian athletes.

AIM & OBJECTIVES OF THE RESEARCH

Aim:

To investigate the impact of training on the steroidal module of the Athlete Biological Passport during different phases of the periodization cycle among Indian Athletes.

Objectives:

i. To study the impact of training during the preparatory phase on the steroidal module in urine.
ii. To study the impact of training during the pre-competition phase on the steroidal module in urine.
iii. To study the impact of training during the competition phase on the steroidal module in urine.
iv. To study the impact of training during the transition phase on the steroidal module in urine.
v. To compare and evaluate the difference in the steroidal module in urine during different phases of the periodization training cycle.

RESEARCH METHODOLOGY

Participants: Indian athletes training at Sports Authority of India (SAI) training centers, representing Individual and/ or team sports disciplines of different ages, heights, and weights who are willing to participate in the study.

Urine Sample: Periodic urine samples will be collected from 36 athletes for the basal value and during the different phases of the periodization training cycle, namely the preparatory, pre-competition, competition, and transition phases**.**

Sample size estimation: A sample size assessment of 36 numbers was conducted by using the GPower software program (version 3.0). The sample size was evaluated for F test and ANOVA: Repeated measures, between factors, for 1 group & 4 follow-up measurements corresponding to four phases, namely preparatory, pre-competition, competition, and transition phases, were chosen.

Eligibility Criteria:

Inclusion:

- Athlete's male & female having an aged 18 years or more.
- Athlete's sample type: urine.

Exclusion:

- Athletes refused to take part in the study.
- The athlete is not part of the SAI-sanctioned training camp.
- Athlete who uses any prohibited substance and/or is reported for an Anti-Doping Rule Violation.
- Athletes with a history of prolonged illness, surgery, medication, disorders etc.
- Athletes reported an Injury during the study.
- Pregnant female athletes.
- Female using contraceptive pills.
- Athletes consuming alcohol.

- As per Laboratory guidelines, samples that are not fit for analysis, such as those compromised by bacterial growth or confounding factors etc, will be excluded.

Ethics: Informed consent will be obtained from the athletes who are willing to participate in the study.

Sampling method: The present study will be non-probability judgmental sampling.

Study design: Time series prospective observational study.

Place of sample collection: SAI training centres.

Duration of sample collection: The duration of urine sample collection will be between three to six months, coinciding with the athletes' periodization cycle designed by the national coach/SAI coach.

Training schedule: The Athlete's periodization cycle or training schedule will be as prepared by the camp National coach/SAI coach.

Procedure:

i. **Permission:** As the first step, the in-charge of SAI centre will be approached to obtain permission to conduct the study on Indian athletes at SAI training centres. Once permission is granted by the authorities, written informed consent will be obtained from the athletes who are willing to participate in the research. Following this, a questionnaire will be distributed in the camp to identify athletes who meet the inclusion and exclusion criteria.

ii. **Urine Sample collection:** Periodic urine samples of 100 ml each will be collected from each of the 36 athletes for basal values and during the different phases of the periodization training cycle, namely the preparatory, pre-competition, competition, and transition phases.

iii. **Sample transportation & storage:** Transportation of the samples will be carried out at a temperature range of 2 to 8°C to minimize degradation. The samples will also be stored in a refrigerator at the laboratory.

iv. **Sample Analysis:** Sample analysis will be done at the National Dope Testing Laboratory (NDTL), New Delhi, a World Anti-Doping Agency-accredited laboratory. After receiving the sample at the laboratory, aliquots will be prepared. Thereafter, the samples will be made to run on ASPEC, GC-MS, and other relevant instruments/techniques to construct the steroidal profile as per the procedure laid in the World Anti-Doping Agency document.

v. **Data interpretation:** Data will be interpreted with the help of the Bayesian Method and will be investigated using Statistical Package for Social Sciences (SPSS). Content will be summarized as Means & Standard deviations. If the data satisfy the requirement of normality, the inferential statistics will be calculated by parametric tests (Repeated measures of ANOVA test), and/or other relevant methods will also be used for the interpretation. The level of statistical significance will be set at 0.05.

OUTCOME MEASURES

i. After receiving the sample, the aliquots of 2 ml will be prepared for analysis. The sample was hydrolyzed with an enzyme to produce a pre-form of steroid, thereafter, the sample was run through automated solid pale extraction chromatography (ASPEC) (*Gilson, USA*) and the sample was derivatization with BSFTA/MSTFA and injected on gas chromatography combined with mass spectrometry (GC-MS) (*Agilent 7000 c, USA*) for determination of steroid profile as per the laboratory guideline.

ii. The sample will also be checked for any bacterial growth by verifying "the ratio 5α-androstenedione (5αAND) to A and 5β androstenedione (5β AND) to Etio are determined based on the concentration of the respective steroid" as per the laboratory guideline.

iii. Further, the confirmation procedure of the steroid profile will be carried out as per the one laboratory guideline.

EXPECTED OUTCOME OF THE RESEARCH

i. At present, Anti-Doping Monitoring Unit (APMU) experts monitor the longitudinal profile of each athlete. If any value from a sample falls outside the athlete's reference range, the experts recommend that the respective Anti-Doping Organization conduct a further follow-up test on the athlete or perform additional confirmation analysis on the sample in question.

ii. Sometimes, the above follow-up tests and confirmation analysis procedures are very expensive and time-consuming.

iii. From this study, it can be concluded that if training has a significant effect on steroidal module or not. Further, this could be one of the considering factors for the APMU experts before any further recommendation which will be very useful in saving money & time for Anti-Doping Organizations.

iv. From an athlete's perspective, frequent exposure of athletes to sample collection during follow-up tests can also be avoided.

OPERATIONAL DEFINITIONS

ADAMS: ADAMS is an online database management tool for data entry, storage, sharing, and reporting to assist stakeholders & World Anti-Doping Agency in their anti-doping operations.

Anti-Doping Organization: World Anti-Doping Agency or a signatory that is responsible for adopting rules for initiating, implementing, or enforcing any part of the Doping Control process. This includes, for example, the International Olympic Committee (IOC), the International Paralympic Committee (IPC), National Anti-Doping Organizations (NADOs) and other Major Event Organizations (MEOs).

APMU: The APMU is the unit of expertise that is responsible for the timely management of Passports in the ADAMS on behalf of the Passport Custodian.

International Standards: Compliance with the World Anti-Doping Agency's International Standard shall be sufficient to conclude that the procedures addressed by the International Standard were performed correctly. International Standards shall include any technical documents issued according to the International Standard.

Competition phase: During this phase, the athlete frequently competes in an event.

Doping Control Officer: A Doping Control Officer (DCO) is an official who has been trained and certified by ADOs and or the sample collection authority.

International Federation: International Federation or International Sports Federations which are responsible for a given sport globally.

Periodization: The periodization of training is the tool that coaches have for athletes to respond to the training load with beneficial adaptations of their sports performance.

Phlebotomy: Phlebotomy is the process in which someone uses a needle to take blood from a vein, usually in your arm.

Pre-Competition phase: This period includes about 2 or 4 weeks before the competition period.

Preparatory phase: This phase refers to the development of the basic athletic attributes-speed, strength power, endurance, flexibility, balance, agility, and ultimately coordination.

Prohibited Methods: Any method so described on the Prohibited List

Prohibited Substance: Any substance, or class of substances, so described on the Prohibited List.

Prohibited List: The list identifying the Prohibited Substances and Prohibited Methods.

Transition phase: The transition phase, often called the off its season, links two annual training plans**.**

World Anti-Doping Agency Code: The World Anti-Doping Agency code is the document that harmonizes regulations regarding anti-doping across all sports and all countries.

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IMPACT OF TRAINING ON STEROIDAL MODULE OF ATHLETE BIOLOGICAL PASSPORT AMONG INDIAN ATHLETES

SHORT SYNOPSIS

Submitted in partial fulfillment of the requirement for the degree of

DOCTOR OF PHILOSOPHY

to

Manav Rachna International Institute of Research and Studies

(Deemed to be a University)

by

Jay Singh

Registration number: 21/Ph.D./090

Under the supervision of

Supervisor

Dr. Anjana Goyal

Anjana Goyal

A Singh

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Designation: Professor & Head

School of Dental Sciences

NAAC Accredited 'A++' Grade University & Professional Institutions

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Department of Biochemistry

School of Allied Health Sciences

Manav Rachna International Institute of Research and Studies,

Sector-43, Suraj Kund –Delhi Road, Faridabad – 121004

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SCHOOL OF ALLIED HEALTH SCIENCES

Certificate

I hereby declare that the short synopsis "Title: Impact of Training on Steroidal Module of Athlete Biological Passport among Indian Athletes" being submitted in partial fulfillment of the requirement for the degree of Doctor of Philosophy

Anjana Goyal

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Vidyaparthshal

Ref No:- ED&Dean Res/1551

OFFICE OF ED & DEAN RESEARCH
Research Ethics Committee
MRIIRS, FARIDABAD
Phone-0129-4198200
Email-dean.research@mriu.edu.in

12th September, 2024

Dr. Anjana Goyal
Supervisor
Professor & Head,
Department of Biochemistry
SDS,MRIIRS
Faridabad- 121001

Dear Dr. Anjana

The MRIIRS Ethics Committee has reviewed your request, for the ethical approval for the research project outlined below.

"*Impact of training on Steroidal module of Athlete BiologicalPassport (ABP) among Indian Athletes*"

Mr. Jay Singh
Research Schlor
Ph.D Programme, MRIIRS
Reg No: 21/Ph.D/090

The case was discussed in the meeting of Ethical Committee, MRIIRS held on 05/09/2024 vide Online Mode at 3.30 pm , the link is given below:

https://meet.google.com/afw-bphq-hwz

On examining the research work undertaken vide video presentation mode given by the Research scholar, the focus of the proposed study is to ,ascertain the impact of an athlete's training load on the steroidal module of their biological passport. For this purpose, athletes' urine samples need to be taken periodically during periodization training cycle, which includes preparatory, pre-competition, competition & transition phases. The sample will be analyzed at a laboratory that is accredited by WADA,. As per the protocol outlined in the WADA technical document, GC-MS shall be used to quantify the markers of the steroid profile.This is not an invasive process. Univariate statistical analysis utilizingone-way ANOVA will be employed, along with a

Bayesian model for data interpretation. The documents required have been submitted to Ethical Committee:

As indicated above, it was resolved that ethical approval may be granted to the Research scholar. The supervisor will monitor the whole study.

The required documents as asked in the meeting have been submitted today i.e. 10.09.2024 by Prof. (Dr.) Dr. Anjana Goyal, Supervisor, School of Dental Sciences, MRIIRS

Approval No:	EC/2023-24/050
Approval Date:	12/09/2024
Expiry Date:	30/11/2026
Ethics Committee Decision	Approved

The standard conditions of this approval are:

a) Conduct the project strictly in accordance with the proposal submitted and granted ethics approval. Including any amendments made to the proposal required by the MRIIRS Ethics Committee.
b) Report (email: dean.research@mriu.edu.in) immediately of any complaints or other issues in relation to the research project which may warrant review of the ethical approval of the project.
c) provide a 'progress report' for every year of approval.
d) provide a 'final report' when the project is complete.
e) advise in writing if the project has been discontinued

Please note that failure to comply with the conditions of approval and the **"INDIAN COUNCIL OF MEDICAL RESEARCH. 2017. NATIONAL ETHICAL GUIDELINES. FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN"** may result in withdrawal of approval for the research project.

Sarita 12.9.24

Dr Sarita Sachdeva
ED & Dean Research
MRIIRS

Dean-Resear
Manav Rachna Internation
of Research & Studie
Sector 43, Aravali Hills, Surajkun
Faridabad, Haryana 121001